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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,096	11/19/2001	Anke Rattenholl	13028-002001	2974

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT PAPER NUMBER

1649

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,096

Applicant(s)

RATTENHOLL ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 9-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 7/3/06 has been entered.
2. The rejection of claims 8 & 20 under 35 U.S.C. 112, first paragraph, for new matter is withdrawn due to the amendment of the claims.
3. Applicant's arguments filed 7/3/06 have been fully considered but they are not deemed to be persuasive.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 8 & 20 stand rejected under 35 U.S.C. 102(b) as anticipated by Edwards et al (U.S. Patent 5,683,894), for the reasons made of record in Paper NOs: 20050124, 20050706 & 20060329, and as follows.

Applicants argue on page 6 of the 7/3/06 response that "Edwards fails to teach or even suggest substantially purified proNGF". In contrast to Applicants' assertions, proNGF isolated from cells is "substantially purified" from the cell lysate, by definition. Secondly, the term "substantially purified" is relative term, in which no degree of purification to homogeneity, etc. is alternatively described within the specification nor recited in the claims. Accordingly,

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although Applicants are permitted to be their own lexicographer, no term may be given meaning repugnant to the usual meaning of the term (see MPEP 608.01 (o)), in regards to the breadth encompassed by any term; especially when the specification fails to specifically define the metes and bounds this term otherwise encompasses. Thus, Applicants' arguments are not on point with that actually recited in the current claims; especially as it relates to "pharmaceutical preparations comprising..." (i.e., open claim language).

Applicants then argue on pages 7-8 of the response that "[a]lthough polyacrylamide is not deemed to be toxic, acrylamide... has been shown to cause cancer and nerve damage", that "the phosphate buffered saline methioned in column 10 of Edwards was used as a pharmaceutical carrier for NGF-beta, not for pro-NGF", that "the Examiner has the burden to show that the pro-NGF preparations described in Edwards were actually active, contrary to an explicit statement made in that reference". In contrast to Applicants' assertions, and as previously made of record, the issue remains that the claims recite open claim language, that other "preparations" of proNGF are disclosed by Edwards (versus that described in column 10), which still are structurally identical with that claimed, that *in arguendo*, PBS is still a well known pharmaceutical carrier that "comprises" water, etc., that polyacrylamide has been used in the art as a carrier in animals, in order to generate antibodies and also "comprises" water, a well known pharmaceutical carrier, and importantly, that nothing in the current claim language distinguishes that claimed from the pro-NGF preparations taught by Edwards. Thus, Applicants' arguments remain not on point with that encompassed by the current claims language; consistent with that held by the courts in *In re Thorpe*, *In re Marosi*, *Ex parte Gray*, *In re Best*, *In re Brown*, *In re Hogan and Banks*, previously made of record.

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6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
September 13, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER